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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,853	06/24/2003	Yung-Nien Chang	4-31401A	9278

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DLA PIPER RUDNICK GRAY CARY US LLP
153 TOWNSEND STREET
SUITE 800
SAN FRANCISCO, CA 94107-1907

EXAMINER

LONG, SCOTT

ART UNIT PAPER NUMBER

1633

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/602,853

Applicant(s)

CHANG ET AL.

Examiner

Scott D. Long

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-96 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 38-96 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

1. Claims 38, 39, 43, 44, 45, 46, 47, 48, 49, 51, 52, 53, 57, 59, 61, 62, 63, 64, 65, 66, 74, 75, 83, 84, 86, 87, 90, 91, 93, and 94 are generic to a plurality of disclosed patentably distinct species comprising:

- A. A specific species of tissue specific enhancers selected from a list consisting of DF3, breast cancer specific enhancer, viral enhancer, steroid receptor enhancer, as recited in claims 41,55.
- B. A specific species of tissue specific promoter selected from a list consisting of MUC1/DF3 promoter, α -fetoprotein promoter, erb-B2 promoter, surfactant promoter, Thymidine Kinase promoter, p21 promoter, cyclin promoter, as recited in claims 40, 54, 67, 76, 85,92.
- C. A specific species of replication essential transcription factor gene selected from a list consisting of E1a, E1b, E2, E4, as recited in claims 60, 68, 69, 70, 71, 72, 77, 78, 79, 80, and 81.
- D. A specific species of coding sequence selected from a list consisting of Thymidine Kinase, Cytosine Deaminase, Purine Nucleoside Phosphorylase, as recited in claims 42, 50, 56, 58, 73, 82, 88, 89, 95, and 96.

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2. Applicant is further required under 35 U.S.C. 121 to elect a single species from each of the categories listed above: A (tissue specific enhancer), B (tissue specific promoter), C (transcription factors), and D (coding sequences), even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

3. The species are distinct, each from the other because of the following reasons:

Adenoviral virions or cells comprising virions recited in species A, B, C, and D, above, are directed to products that are functionally distinct and capable of separate use. Tissue specific enhancers function to aid DNA transcription through the binding of transcription factors. However, the enhancer DNA, itself, is never translated into proteins. An enhancer without a promoter could not cause DNA transcription. Tissue specific promoters are DNA sequences that are absolutely necessary for DNA transcription in specific tissues. Their DNA is distinct from the other species, listed in A,

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C, or D. Transcription factor gene products are proteins that control the transcription of a downstream gene, after binding DNA enhancer or promoter sequences. The coding sequences, from D, above, are translated into proteins that can perform a specific enzymatic function.

4. Because these species are structurally distinct for the reasons given above, and because a search of one does not necessarily overlap with that of another species, it would be unduly burdensome for the examiner to search and examine all of the subject matter being sought in the presently pending claims, and thus, restriction/species election for examination purposes as indicated is proper.

5. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Applicant is advised that the response for this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott Long whose telephone number **(571) 272-0948**. The examiner can normally be reached Monday through Friday, between 9:00 am-5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on **(571) 272-0731**. The fax phone number for the organization where this application or proceeding is assigned is **(571) 273-8300**.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

For all other customer support, please call the USPTO Call Center (UCC) at **(800) 786-9199**.

Scott Long.
Examiner, USPTO, AU 1633



DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER